

Serial No.: 10/500,213
Atty. Docket No.: P69868US0

Listing of Claims:

This listing of claims will replace all prior versions, and listings of claims in the present application.

1. (Currently Amended) Immediate-release pharmaceutical or nutraceutical micronized powder having a particle size of at most 100 μm and comprising ~~the~~ a combination of at least one active substance, at least one wetting agent and at least one diluent.
2. (Original) Powder according to Claim 1, characterized in that it has a particle size of at most 50 μm .
3. (Original) Powder according to Claim 1, characterized in that it has a particle size of at most 10 μm .
4. (Previously Presented) Powder according to Claim 1, characterized in that it allows the dissolution of all of the active substance(s) in less than 30 seconds, when it is administered mucosally.
5. (Previously Presented) Powder according to Claim 1, characterized in that the active substance is in a micronized form.

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6. (Currently amended) Powder according to Claim 1, ~~characterized in that the~~ wherein the active substance is at least one member selected from the group consisting of cyproterone acetate, norethisterone acetate, progesterone, 3-keto-desogestrel, norgestimate, laevonorgestrel, desogestrel, gestodene, a natural estrogens, ~~a such as estradiol and derivatives thereof~~, synthetic estrogens ~~such as ethinylestradiol~~, Δ -4-androstenedione, testosterone, dihydrotestosterone, ~~or~~ androstanolone, DHEA, trinitrine, fentanyl, nitroglycerine, nicotine (nicotine S(-)), scopolamine, clonidine, isosorbide dinitrate, alclometasone dipropionate, phloroglucinol, molsidomine, acetazolamide, acyclovir, adapalene, alclomethasone dipropionate, amcinonide, ameline, bamethan sulphate + escin, betamethasone valerate, betamethasone dipropionate, bufexamac, caffeine, calcipotriol monohydrate, cetrimonium bromide, clobetasol propionate, crilanomer, desonide, dexpanthenol, diclofenac, diflucortolone, valerate, difluprednate, diphenhydramine hydrochloride, econazole nitrate, erythromycin, flumetasone pivalate, fluocinolone acetonide, fluocinodine, fluocortolone, fluocortolone hexanoate, fluocortolone pivalate, hydrocortisone, hydrocortisone acetate, ibacitabine, ibuprofen, imiquimod, ketoconazole, ketoprofen, lidocaine, metronidazole, miconazole nitrate, minoxidil, niflumonic acid, penciclovir, benzoyl peroxide, piroxam, iodinated povidone, promestriene, pyrazinobutazone, roxithromycin, sulphacetamide, triamcinolone, tazarotene, tretinoin and isotretinoin, triclocarban, vidarabine monophosphate, β -3-adrenergic agonist, growth hormone, oxybutinin, buprenorphine, pergolide, nestorone, 7α -methyl-19-nortestosterone, mecamlamine, salbutamol, clenbuterol, selegiline, buspirone, ketotifen, lidocaine, ketorolac, eptazocine, insulin, α -interferon, prostaglandins, 5-aminolevulinic acid, benzodiazepine alprozolam, diclofenac, fenoprofen, flubiprofen, ketoprofen, methyl phenidate,

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miconazole, piroxicam, bruprenorphine, alprozolam, dexmedetomidine, prazosin (α -adrenergic antagonist), alprostadiol, tulobuterol (α -adrenergic agonist), ethinyl oestradiol + norelgestromin, ketorolac, physostigmine, medindolol (β -adrenergic agonist), rotigotine (dopamine D2 antagonist), thiatolserine, Esomeprazole, Melagatran (in the case of thrombosis), Rosuvastatin, Ezetimide, Pitavastatin (hyperlipidaemia), Mitiglinide (type II diabetes), Cilomilast, Viozan (asthma), Aripipazole (psychiatry), Omapatrilat (hypertensive), Orzel (cancerology), Caspofongin acetate, Voriconazole (infections), ~~a new COX inhibitors such as Etoricoxib (inflammation)~~, Valdecoxib (arthritis) and Parecoxib, Substance P antagonist (depression), Darifenacin (urology), Eletriptan (migraine), Alosetron, Tegaserod, Capravirine (HIV), Finasteride (5-alpha reductase inhibitor) ~~and combinations thereof~~.

7. (Currently Amended) Powder according to Claim 1 wherein the active substance is at least one member characterized in that the active substance(s) is (are) selected from the group consisting of a vitamin, an comprising vitamins, inorganic salts, and brewer's yeast.

8. (Currently Amended) Powder according to Claim 1, wherein characterized in that the wetting agent is at least one member selected from the group consisting of a polyols such as sorbitol, or glycerin, PEG, hexylene glycol, triacetin, a hydrogenated vegetable oils such as hydrogenated castor oil, a polyoxy(ethylene)polyoxy(propylene) copolymers such as Lutrol® F68, and a polyoxyethylene alkyl ethers such as the Cremophor7, and mixtures thereof.

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9. (Currently Amended) ~~Use of a powder~~ Powder according to Claim 1, wherein ~~characterized in that~~ the diluent is at least one member selected from the group consisting of calcium or sodium carbonate or bicarbonate, sucrose, mannitol, xylitol, sorbitol, lactose, maltitol, glucose, cellulose, a or microcrystalline cellulose powder, starch, a starch and its derivatives, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulphate, a dextrates, a dextrans, a dextrose excipients, fructose, kaolin, and lactitol ~~and mixtures thereof~~.

10. (Previously Presented) Powder according to Claim 1, characterized in that it further comprises an antistatic agent.

11. (Original) Powder according to Claim 10, characterized in that the antistatic agent is selected from the group consisting of colloidal silica, magnesium silicate, talc, calcium silicate and tribasic calcium phosphate and mixtures thereof.

12. (Currently Amended) Powder according to Claim 1, which ~~characterized in that~~ it further comprises a binder which is at least one member ~~may be~~ selected from the group consisting of acacia, alginic acid, carboxymethyl cellulose sodium, microcrystalline cellulose, a dextrans, ethyl cellulose, gelatin, glucose, guar gum, hydroxypropyl methyl cellulose, methyl cellulose, polyethylene oxide, povidone, and pregelatinized starch ~~and mixtures thereof~~.

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13. (Currently Amended) Powder according to Claim 1, which ~~characterized in that it~~ further comprises an absorption enhancer selected from the group consisting of an aliphatic fatty acid esters ~~such as isopropyl myristate, a~~ fatty acids ~~such as oleic acid, a~~ an alcohols or polyols, ~~such as ethanol, propylene glycol and polyethylene glycol; the~~ a components of an essential oils, a and terpene derivatives, a (such as ~~eugenol, geraniol, nerol, eucalyptol, menthol~~); surfactants, a preferably non ionic, ~~such as polyoxyethylene sorbitan (fatty acid ester), polyoxyethylene alkyl ether, polyoxyethylene derived from castor oil; moisturizers, a~~ such as ~~glycerin, urea, keratolytic agents, such as alpha-hydroxy acids (lactic acid, citric acid, etc), 23-lauryl ether, aprotinin, azone, benzalkonium chloride, cetylpyridinium chloride, cetyltrimethylammonium bromide, a~~ cyclodextrins, dextran sulphate, lauric acid, lysophosphatidylcholine, a menthol, methoxysalicylate, methyl oleate, oleic acid, phosphatidylcholine, polyoxyethylene, polysorbate 80, sodium EDTA, sodium glycocholate, sodium glycodeoxycholate, sodium lauryl sulphate, sodium salicylate, sodium taurocholate, sodium taurodeoxycholate, a sulphoxides, and an alkyl glycosides ~~and mixture thereof.~~

14. (Previously Presented) Powder according to Claim 1, characterized in that it further comprises an edulcorant agent and/or a flavoring agent.

15. (Original) Powder according to Claim 14, characterized in that the edulcorant agent is selected from the group consisting of aspartam, dextrates, dextrose, fructose, mannitol, sodium or calcium saccharinate, sorbitol, sucralose, sucrose, and mixtures thereof.

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16. (Currently Amended) Powder according to Claim 14, wherein ~~characterized in that~~ the flavoring agent is at least one member selected from the group consisting of a flavors of synthetic, semi-synthetic or natural origin, ~~such as for example mint, peppermint, lemon, banana, strawberry, raspberry, mandarin, orange, vanilla, passion fruit, caramel, and the mixtures thereof.~~

17. (Previously Presented) Powder according to Claim 1, characterized in that it is in a form suitable for its application on the buccal mucosa, the nasal mucosa or the vaginal mucosa.

18. (Previously Presented) Powder according to Claim 1 characterized in that it is in a form suitable for its application to the buccal mucosa sublingually.

19. (Previously Presented) Powder according to Claim 1, characterized in that it is in a sprayable form.

20. (Previously Presented) Powder according to Claim 1, characterized in that it is packaged in a single-dose packet.

21. (Previously Presented) Powder according to Claim 1, characterized in that it is packaged in a thermally moulded capsule provided with a peelable operculum.

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22. (Previously Presented) Powder according to Claim 1, characterized in that it is in a packaging suitable for powder administration known to those skilled in the art.

23. (Canceled)

24. (New) Powder according to claim 6 wherein the active substance is at least one member selected from the group consisting of estradiol, a natural estradiol derivative, ethinylestradiol, and Etoricoxib (inflammation).

25. (New) Powder according to claim 8 wherein the wetting agent is at least one member selected from the group consisting of PEG, hexylene glycol, triacetin, and a hydrogenated vegetable oil.

26. (New) Powder according to claim 13 wherein the absorption enhancer is at least one member selected from the group consisting of isopropylmyristate, oleic acid, ethanol, propylene glycol, polyethylene glycol, eugenol, geraniol, nerol, eucalyptol, menthol, polyoxyethylene sorbitan, polyoxyethylene alkyl ether, polyoxyethylene derived from castor oil, glycerin, urea, and an alpha-hydroxy acid.

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27. (New) A method for manufacturing an immediate-release pharmaceutical or nutraceutical composition, said method comprising a step of micronizing a composition comprising a combination of at least one active substance, at least one wetting agent and at least one diluent.